grafting PEI to said hydrogel coated metallic medical device to form a PEI coated metallic medical device.

32. (Amended) A medical device having a PEI coating according to claims 29, 30, or 31.

REMARKS

Claims 15-32 of the present application are currently pending. In the Final Office Action dated June 4, 2002, claims 20 and 25-28 were rejected under 35 U.S.C. §112 and claims 15-17, 20, and 23 were rejected under 35 U.S.C. §102(b). In addition, claims 19 and 32 were objected to under 37 CFR 1.75(c) as being in improper multiple dependent form.

The Applicants note with appreciation that the Examiner indicated that claims 29-31 are allowable and claims 18 and 24 have objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claims.

In response, each one of the cited references has been reviewed and the rejections and objections made to the claims by the Examiner have been considered. Claims 18, 21, and 24 have been cancelled and claims 15, 19, 20, 22, 23, 25, 29, and 32 have been amended to more clearly recite the novel features of the presently claimed invention.

For the reasons set forth below, it is submitted that all the pending claims are in condition for allowance and allowance of the application is respectfully requested.

Rejections under 35 USC §112

In the Final Office Action dated June 4, 2002, claim 20 was rejected under 35 U.S.C. §112, first paragraph, for not reasonably providing enablement for "preventing" restenosis, and claims 25-28 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner asserted that lines 3-5 of claim 25 are confusing.

In response, the Applicants have amended claims 20 and 25 of the present application to more clearly recite and define the novel aspects of the presently claimed invention. As a result, the Applicants respectfully submit that the claims as presented in

the amendment conform to all applicable requirements under 35 U.S.C. §112 and that the rejections be withdrawn.

Claim Objections

In the Final Office Action dated June 4, 2002, claims 19 and 32 were objected to under 37 CFR 1.75(c) as being in improper multiple dependent form. In addition, claims 18 and 24 were objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form to include all the limitations of the rejected base claim and any intervening claims.

In response, the Applicants have amended claims 19 and 32 to conform with 37 CFR 1.75(c). In addition, the Applicants have cancelled claims 18 and 24, and amended claims 15 and 23 to include the limitations of claims 18 and 24, respectively. As such, the Applicants respectfully submit claims 15, 19, 23, and 32 are in condition for allowance and allowance is respectfully requested.

Rejections under 35 USC §102

In the Office Action dated June 4, 2002, independent claims 15, 20, 23 and dependent claim 16 were rejected under 35 USC §102(b) as being anticipated by United States Pat. No. 5,770,645, issued to Stamler et al. (hereinafter *Stamler '645*). In addition, independent claims 15, 20, and 23 and dependent claim 17 were rejected under 35 USC §102(b) as being anticipated by United States Pat. No. 5,873,904, issued to Ragheb et al. (hereinafter *Ragheb '904*). For the reasons set forth below, the Applicants respectfully traverse the rejections and respectfully submit that the pending claims define patentable subject matter over the cited prior art.

The present invention is directed to nitric oxide releasing metallic medical devices. More specifically, claim 15 of the presently claimed invention pertains to a medical device for treating or inhibiting restenosis and includes a vascular stent having a surface comprising a lubricious coating wherein nitric oxide-releasing nucleophilic compounds are disposed throughout the lubricous coating in a three dimensional matrix. More particularly, the nitric oxide-releasing nucleophilic compound comprises a diazeniumdiolate.

Claim 20 of the presently claimed invention is directed to a method for treating or inhibiting restenosis and comprises providing a medical device having a polymer

coating comprising a compound having combined cytostatic, antithrombogenic, vasodilatory and antiproliferative effects applied thereto, and delivering the medical device to the treatment area such that said compound is released from the medical device in a controlled fashion. The compound of the polymer coating may comprise a diazeniumdiolate.

Claim 23 of the presently claimed invention pertains to a method for providing a metallic medical device with a surface having multi-functional molecules and includes applying an amine-fuctionalized silane to a metallic surface for a time sufficient and under conditions suitable for the binding of the amine-fuctionalized silane to the metallic surface. The amine-fuctionalized silane is selected from the group consisting of 4,7,10-triazadecyl-trimethoxysilane, 3-aminopropyltriethoxysilane, trichlorovinylsialane, 3-aminopropyltrimethoxysilane, 3-aminopropyldiisopropylethoxysilane, and 3-aminopropylmethyldiethoxysilane.

In the Final Office Action dated June 4, 2002, the Examiner stated claims 18 and 24 of the presently claimed invention were objected to as being dependent on a rejected base claim, but would be allowable if re-written in independent form to include all the limitations of the base claim and any intervening claims. In response, the Applicants have cancelled claims 18 and 24 and amended claims 15 and 23 to recite the novel features of the presently claimed invention disclosed in claims 18 and 24.

Furthermore, the Applicants have amended claim 20 to recite the novel feature of applying a diazeniumdiolate to a medical device to treat or inhibit restenosis. Neither the *Stamler '645* reference nor the *Ragheb '904* reference teach or suggest applying a diazeniumdiolate to a medical device.

For at least the reasons stated above, it is respectfully submitted that independent claims 15, 20, and 23 are not anticipated by either the *Stamler '645* reference or the *Ragheb '904* reference. Moreover, for at least the same reasons, it is submitted that dependent claims 16 and 17 are also patentable.

Conclusion

For the foregoing reasons, all claims presently on file in the subject application are in condition for immediate allowance, and such action is respectfully requested.

If it is felt for any reason that direct communication with applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is invited to call the undersigned attorney at the below listed telephone number.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changed made**."

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1901.

Respectfully submitted,

October 31, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In The Claims

Please cancel claim 18, 21, 24 and amend claims 15, 19, 20, 22, 23, 25, 29, and 32 as follows:

15. (Amended) A medical device for treating or inhibiting restenosis comprising:

a vascular stent having a surface comprising a lubricious coating wherein nitric oxide- releasing nucleophilic compounds are disposed throughout said lubricious coating in a three dimensional matrix, wherein said nitric oxide-releasing nucleophilic compound [is]comprises a diazeniumdiolate.

19. (Amended) The medical [devise]device according to [and one of]claims 15, 16, or 17[, or 18] wherein said three-dimensional matrix comprises multiple layers of nitric oxide-releasing nucleophiles entrapped within said three dimensional matrix.

20. (Amended) A method for treating or [preventing]inhibiting restenosis comprising:

providing a medical device[s] having a polymer coating applied thereto, said polymer coating comprising a compound having combined cytostatic, antithrombogenic, vasodilatory and antiproliferative effects, wherein said compound comprises a diazeniumdiolate; and

delivering said medical device to [the]a treatment area such that said compound is released from said medical device in a controlled fashion.

22. (Amended) The method according to claim [19]20 wherein said medical device is selected from the group consisting of stents, grafts, guide wires, and catheters.

23. (Amended) A method for providing a metallic medical device with a surface having multi-functional molecules comprising:

applying an amine-fuctionalized silane to a metallic surface for a time sufficient[,] and under conditions suitable for binding said amine-fuctionalized silane to [bind to]said metallic surface, wherein said amine-fuctionalized silane is selected from

the group consisting of 4,7,10-triazadecyl-trimethoxysilane, 3-aminopropyltriethoxysilane, trichlorovinylsialane, 3-aminopropyltrimethoxysilane, 3-aminopropyldiisopropylethoxysilane, and 3-aminopropylmethyldiethoxysilane.

25. (Amended) A method for providing a metallic medical device with a surface having multi-functional molecules comprising:

applying a reactive isocyanatosilane to a metallic surface for a time sufficient[,] and under conditions suitable for binding said amine-fuctionalized silane to [bind to]said metallic surface; and

coupling a nucleophile to said reactive isocyantosaline.

29. (Amended) A method for providing a metallic medical device with a polyethylenimine (PEI) coating comprising:

cleaning [sad]said metallic medical device;

applying an amine-fuctionalized silane to said cleaned metallic medical device to form a silanized metallic medical device;

forming a hydrogel coating on said silanized metallic medical device to form a hydrogel coated metallic medical device; and

grafting PEI to said hydrogel coated metallic medical device to form a PEI coated metallic medical device.

32. (Amended) A medical device having a PEI coating according to[any one of] claims 29, 30, or 31.